

**Becton Dickinson VACUTAINER Systems**

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**G. SUMMARY OF SAFETY AND EFFECTIVENESS**

**G.1. Summary**

**Submitter:** Eileen Schweighardt  
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1 Becton Drive  
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**Date:** December 19, 1996

**Device:** VACUTAINER® Brand Safety-Lok™ Blood Collection Set

**Classification:** Accessory To: Tubes, Vials, Systems, Serum Separators, Blood Collection (75JKA)

**Predicate Device:** VACUTAINER® Brand Safety-Lok™ Blood Collection Set

**Intended Use and Product Description:** A needle and attached tubing for venipuncture and the collection of blood specimens from patients. Includes a safety shield to minimize the possibility of needlesticks.

**Proposed Modification:** Alternate manufacturing site and alternate material suppliers.

Becton Dickinson VACUTAINER Systems has determined that the establishment of an additional manufacturing site and alternate material suppliers does not affect the safety or effectiveness of the product for its intended use. Testing has shown that functional performance of the product is equivalent to the current product.

There are no new product claims associated with this 510(k).

### **Synopsis of Test Methods and Results**

Equivalent functional performance is demonstrated between the current Safety-Lok™ Blood Collection Set and the modified Safety-Lok™ Blood Collection Set in a study comparing flow rates; shield activation force; shield sustaining force; shield override force; heat stake break force; pressure testing; I.V. penetration and drag forces. The studies identified some differences; however these differences will not affect the overall performance of the modified product.

A simulated use study was conducted to evaluate the ease of package opening, ease of safety shield activation, ease of disposal and successful activation of the safety shield of the modified Safety-Lok™ Blood Collection Set manufactured by BDVS in comparison to the current Safety-Lok™ Blood Collection Set manufactured by Nissho. The principal device manufactured by the BDVS demonstrated equivalent or improved ease of package opening/product accessibility, shield activation and disposal. The Simulated Use and Actual Use studies for successful safety shield activation exhibited successful activation for both the principal and predicate devices.

  
Eileen Schweighardt  
Manager, Regulatory Affairs

12/23/96.  
Date